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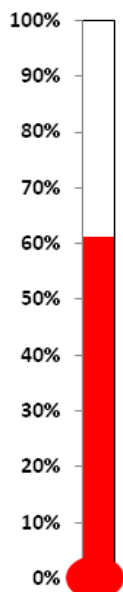
Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 8/24/2015

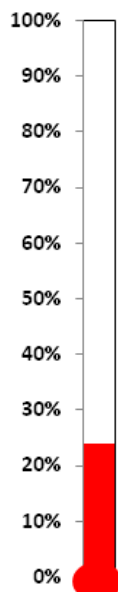
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Trial Status: 8/17/2015-8/24/2015

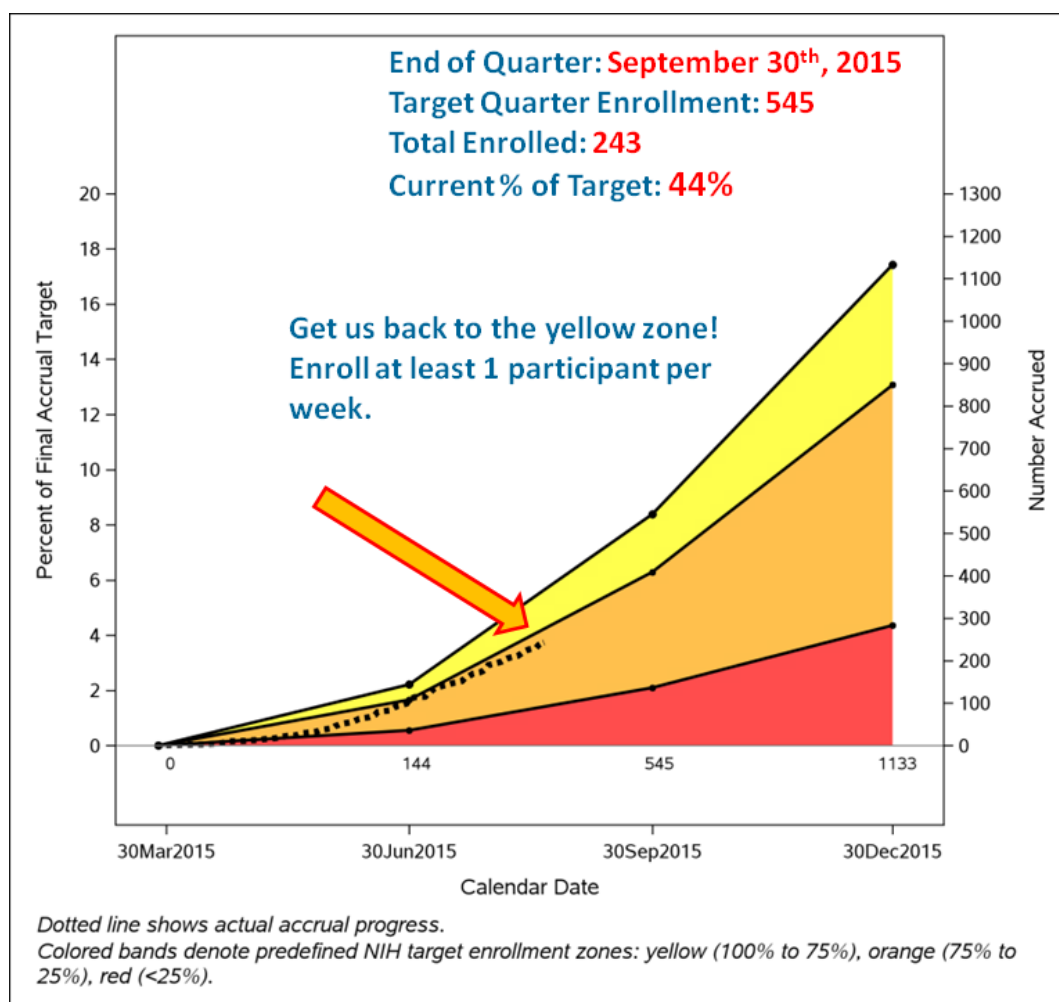


61% of Activated Sites are Enrolling!



24% of Activated Sites Enrolled at Least 1 Participant Last Week!**

****Our goal is 100%, we need 100% of activated sites to enroll 1 participant each week.**



Congratulations to Sites Enrolling Participants Week of 8/17/15

Greensboro CRS

UCSD Antiviral Research Center CRS
Cincinnati CRS
Puerto Rico AIDS Clinical Trials Unit CRS
Northwestern University CRS
Ohio State University CRS
Case CRS
The Miriam Hospital CRS
Cornell Chelsea CRS
University of Rochester Adult HIV Therapeutic Network CRS
Whitman Walker Health CRS
Duke University Medical Center
AIDS Research Treatment Center of the Treasure Coast

**Help Make REPRIEVE a Success:
Enroll at Least 1 Participant per Week!**

FAQ



If a potential participant already has all the labs from a clinical visit (including a fasting lipid panel) required for screen, can she/he skip the screen and proceed to the entry visit?

If all screening labs are available from standard of care within the specified collection windows, then the remaining screening evaluations (e.g., screening physical exam, height, weight, waist circumference) and entry evaluations may be performed on the same day. Please see the Protocol Section 6.1, Schedule of Events for additional details.

Is it okay if a potential participant had a change in the individual medications of their combination antiretroviral regimen 40 days prior to screen but has been on combination antiretroviral therapy for 3 years?

Yes, as long as the participant has been on continuous antiretroviral therapy for the past 30 days (meaning no breaks) and on combination antiretroviral therapy (ART) for at least 180 days prior to study entry.



Study Medication Tips to Review with Participants

Using simple, everyday language, please briefly review the following with study participants at every visit post screen.

- Name of study medication
- Indication for pitavastatin and why it is being studied in REPRIEVE (use language from Consent Form).
- Dose, route, and frequency of study medication administration. Remind participants that the study medication should be taken at the same time each day, with or without food.
- In order for the study medication to work effectively, it must be taken every day
- **Instruct participants to take ONE tablet per day and to complete one bottle before starting another**
- All study medication will be supplied by the study
- Review potential side effects related to study medication
- If a dose of study medication is missed, take the next scheduled dose

Note: The language above is from the A5332 MOPS except for what is highlighted in red, this language will be included in the next version, likely to be released in early September.

The first Clarification Memo made performing the pregnancy test easier!

See the attached [clarification memo](#) and the language below from the memo:

The REPRIEVE (A5332) inclusion criterion 4.1.6 is clarified to include clinics, as follows:

Females of reproductive potential....must have a negative serum or urine pregnancy test within 48 hours prior to entry by any US laboratory **or clinic** that has a CLIA certification or its equivalent, **or is using a point-of-care (POC)/CLIA-waived test**, or at any network-approved non-US laboratory **or clinic** that operates in accordance with Good Clinical Laboratory Practices and participates in appropriate external quality assurance programs.

RECRUITMENT

Recruitment Tip of the Week: Actively Recruit!

Examples of active recruitment include:

1. Utilize databases from previous studies that identify eligible participants who may be interested in REPRIEVE.
2. IRB approved review of medical records to identify eligible participants
3. IRB approved use of searchable electronic medical record in your clinic/hospital to filter out potential participants based on inclusion/exclusion criteria.
4. Collaborate with local providers to refer pre-qualified participants.
5. Offer community presentations to providers and people living with HIV.

Featured Site! Houston AIDS Research Team!



The Houston AIDS Research Team has enrolled 20 participants in REPRIEVE! Below they have shared some of their best practices for recruitment.

1. Work closely with primary care physicians to identify participants

We currently have our CRS research coordinators actively working with physicians at the

clinic to identify participants for REPRIEVE. Our CRS always has a research coordinator available during clinic hours.

2. Have primary care physicians introduce REPRIEVE to patients

Our site has found that eligible candidates are more likely to accept to participate in the study when it is first introduced and explained in detail by the primary care physician.

“Having the primary care provider explain the background of the study and discuss the risks and benefits of the strategy, study procedures and investigational drugs, brings more confidence and interest to the potential participants, facilitating their recruitment.” Dr. Roberto C. Arduino.

3. Enroll participants from prior studies

Prior study participants are a great source and good candidates for REPRIEVE.

Our participants state as long term HIV patients, they have experienced the benefits of research studies and new medicines. They understand the impact of their participation on their community and realize it is a win-win situation.

4. Fluent communication with participants

Communication is very important in the recruitment for REPRIEVE. Explaining study requirements and visit schedules, answering participants' questions about REPRIEVE, helps candidates decide that participating is a good choice for them.

Training Opportunities



TRAINING OPPORTUNITIES

All training call dates and call details are listed on the public [REPRIEVE website calendar](#).

Future ECG Training

2 additional ECG training webinars will be offered!

- Thursday, September 10th, 11:00AM-11:30AM ET
- Thursday, October 1st, 2:00PM-2:30PM ET

An announcement will be sent via email. Please note, participation by your site is mandatory for

site activation. Please also feel free to join if you would like a refresher.

Monthly Site Calls

Monthly Site Calls are held the 3rd Tuesday of each month at 1PM ET. Barbara Bastow sends out the email announcement regarding these calls. During these calls, the team tries to address questions raised by sites during the previous month and we are available to answer any questions during these calls. Please bring questions and REPRIEVE tips to these calls, this is a great opportunity to talk to the team and share what's working well at your site!

Did you know...

The **REPRIEVE Site Selection and Performance Committee (SSPC)**, has begun to evaluate site performance and will focus their efforts on evaluating Recruitment, Retention, Data and Specimen Management as well as observations from site monitoring visits. The members of the committee will be reaching out to sites if certain performance measures are not met. The intent of the evaluation is to ensure the success of REPRIEVE. Please read the Site Performance Plan located on the [A5332 PSWP](#), in the Site Performance folder for more details.

What is in the Folders on the REPRIEVE (A5332) PSWP?

What is in the "Site Activation" folder?

- Hard copies of the site activation checklist.
- A presentation giving an overview of the ACTG Member website and instructions on how to find the REPRIEVE study, your site record, the protocol-specific web page (PSWP), and site activation documents.
- Detailed instructions on completing site activation and how to submit the checklist online.
- If you have any questions about the Site Activation process, email ACTGSiteCoordination@s-3.com.

Did you know that there are tools you can customize and use at your site available on the PSWP?

Staff from other sites has shared their flow sheets and checklists so you won't have to start from scratch. The use of these tools is not required and you should check them for accuracy before using, but they can save you time!

In the Protocol Training folder, under "Optional Tools" you'll find the following:

- Flowsheets for ARVs, conmeds, and diagnoses
- Checklists for Screening, Entry, On-Study, and Return Fasting Visits
- Checklists for Signs and Symptoms, Study Treatment, Entry Verification, and Vital

Signs

- Participant Cards - for patients to share with care providers that explain they are on a randomized statin study.
- A Visit Schedule for participants.
- Phone screen sheet
- Combined screen sheet if your participant will also enroll in The Mechanistic Substudy A5333s.
- Please let us know if you have any helpful tools you wish to share!

JUST POSTED on the A5332 PSWP

Site Performance Plan, dated 8/06/15

(read this to see how the REPRIEVE Site Selection and Performance Committee is evaluating site performance)

Corrected [Myalgia Symptom Assessment questionnaire](#) (Spanish version), located in Protocol-Specific Support Documents (Version 2.0), Spanish Translations on the A5332 PSWP

"Coenrollment Guidelines" was updated to allow coenrollment with A5337 (Safety and Efficacy of Sirolimus for HIV Reservoir Reduction in Individuals on Suppressive ART) in certain circumstances.

These documents are on the [A5332 PSWP](#)

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 6/15/2015

A5332 LPC for ACTG Sites:

dated 7/30/15

A5332 LPC for Non-ACTG Sites:

dated 7/30/15

These documents are on the [A5332 PSWP](#)

REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

For A5333s please use

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 3/16/2015

A5333s LPC : dated 7/30/15

These documents are on the [A5333s PSWP](#)

For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at reprieve.news@fstf.org.

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